CODEX ALIMENTARIUS COMMISSION

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CODEX COMMITTEE ON CONTAMINANTS IN FOODS

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MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN CERTAIN CEREALS AND CEREAL-BASED PRODUCTS INCLUDING FOODS FOR INFANTS AND YOUNG CHILDREN

(At Step 4)

(Prepared by the Electronic Working Group chaired by Brazil and co-chaired by India)

Codex members and observers wishing to submit comments at Step 3 on this document should do so as instructed in CL 2021/15/OCS-CF available on the Codex webpage[1]

BACKGROUND

1. The Codex Committee on Contaminants in Foods (CCCF) has been discussing the establishment of maximum levels (MLs) for total aflatoxins (Afs), namely the sum of aflatoxins B_1, B_2, G_1 and G_2) in cereals and cereal-based foods since 2013. CCCF13 (2019) considered a discussion paper containing data available in the GEMS/Food database on the occurrence of AFs in cereal and cereal-based products, including cereal-based food for infants and young children, and focusing on maize, rice, sorghum, wheat and flours of these cereals.

2. The discussion paper showed[2] that there is a large dataset available on the occurrence of AFs in cereals and cereal-based products in the GEMS/Food database (more than 17000 samples), submitted mainly by the European Union (EU), Singapore and Canada. The discussion paper also demonstrated that the establishment of any MLs for AFs in maize grain, flour, meal, semolina and flakes derived from maize, husked and polished rice, wheat grain, flour, meal, semolina and flakes derived from wheat could greatly reduce total AFs exposure worldwide, as already stated by the Joint FAO/WHO Committee on Food Additives (JECFA) (TRS 1002-JECFA 83/11).

3. While there was general support for the establishment of maximum levels (MLs), observations were made that the work should be based on more geographically representative data. It was noted that occurrence data in cereals used for the analysis and the subsequent proposal for new work, relied heavily on data from only a few countries and regions. Although calls for data on the occurrence of AFs in cereals and cereal-based products have been made since 2014, CCCF13 pointed out that the available data were not sufficiently representative of cereal-based foods from all GEMS/Food cluster diets.

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[1] Codex webpage/Circular Letters:
http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/.
Codex webpage/CCCF/Circular Letters:
http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCCF

[2] CX/CF 19/13/15

4. CCCF13 therefore agreed to establish an Electronic Working Group (EWG) chaired by Brazil and co-chaired by India to present at its next session proposals for MLs for total AFs in maize grain destined for further processing, flour, meal, semolina and flakes derived from maize, husked and polished rice (excluding parboiled rice), cereal-based food for infants and young children and sorghum. The Committee further agreed to include sorghum in the list noting that it was a staple food in many parts of the world and that once the work on the MLs for the food categories mentioned above were completed, the proposal of MLs for other cereals and cereal-based products should be considered. The proposals for MLs will consider both the impact on the AF exposure and the sample rejection rate. There was also agreement that a call for data[3] should be issued on whole wheat flour and parboiled rice to better assess whether these food categories should be added later.[4]

5. The 42nd Session of the Codex Alimentarius Commission (CAC42, 2019) approved[5] the new work as proposed by CCCF13.

6. CCCF14 was postponed from May 2020 to May 2021 due to the COVID-19 pandemic and in view of the additional time at the disposal of the Committee, an interim report of the EWG was published as CX/CF 20/14/10-Part I. Comments were requested through CL 2020/23/OCS-CF for further consideration by the EWG. The comments received in reply to this CL were compiled in CX/CF 20/14/10 Add.1.

7. Working documents issued during 2020, which has been revised or updated in 2021 for consideration by CCCF14, can be found on the Codex website[6].

8. This paper addresses key points raised in response to CL 2020/23/OCS-CF as described below. The MLs and background information providing the rationale for the proposed MLs previously contained in CX/CF 20/14/10 remain unchanged. The EU requested to withdrawal data that have been provided by individual EU Member States and were not recognized by EFSA as input from GEMS/Food Database. This removal led to the modification of a few rejection rates in the scenarios previously presented. Moreover, a typo was also identified in the rejection rate of proposal 2 for cereal-based food for infants and young children.

KEY POINTS RAISED IN RESPONSE TO CL 2020/23/OCS-CF

9. The following points were raised by some or individual Codex members / observers:

Comments provided by some Codex members

- <u>Geographic representation of the samples</u>

  Data available at the GEMS/Food database came mostly from the United States of America (USA) and EU, even though calls for data on the occurrence of AFs in cereals and cereals-based products have been made since 2014. Analysis of data grouped by continent, country and year of sampling showed that the mean level of AFs (lower bound) and the resulting impact of the proposed MLs for each food category did not significantly vary. Considering the lack of geographically representativeness of the data available, it has been suggested that the MLs for AFs in cereals and cereals products should be reviewed 3 years after its adoption. Moreover, CCCF must consider the toxicological relevance of AFs and how the establishment of MLs for these food categories could greatly reduce human exposure to these mycotoxins.

- <u>Rationale used to propose MLs for each food category</u>

  The rationale used to propose the different MLs was based on the profile of contamination of each food category. After creating histograms and determining the P95 for the AFs occurrence in samples submitted to the GEMS/Food database, MLs were proposed considering a maximum rejection rate of 5%. A preliminary exposure assessment was carried out to illustrate the expected intake reduction of each ML proposed to support risk management decisions. After that, a ML was recommended based on the combination of expected intake reduction and sample rejection rates. Another point considered was the rejection rate accepted for grains and processed products. For example, grains that not met human consumption standards may be destined for animal feed, which would not be possible for processed products. Therefore, CCCF should discuss what rejection rate would be appropriate for these different types of products, considering both food security and AFs intake reduction.

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[3] JECFA calls for data are available at: http://www.fao.org/food-safety/scientific-advice/calls-for-data-and-experts-expert-rosters/en/

[4] REP19/CF, paras. 146-155, Appendix IX

[5] REP19/CAC, Appendix V

[6] http://www.fao.org/fao-who-codexalimentarius/meetings/extra/cccf14-2020/en/

- Presence of outliers on the dataset

  Considering that CCCF has not yet agreed upon a procedure to deal with outliers in datasets of heterogeneous distributed contaminants and considering the possibility of samples being really contaminated with high levels of AFs, it was decided not to remove the possible outliers from the data sets considered in this document. Furthermore, the presence of the possible outliers in the dataset did not impacted the proposal of MLs since they had no effect on the 95 percentiles. In addition, the Committee should consider that aflatoxin contamination of cereals does not follow a normal distribution and several factors can influence AFs production, including climatic factors, which may change from year to year.

Comments provided by individual Codex members

- Exclusion of data related to Individual EU Member States from the dataset used in this document

  Considering that occurrence data on contaminants in food in the EU are provided to the GEMS/Food by EFSA on behalf of all EU Member States, the EU questioned that the origin of the few data reported as Individual Member States was unclear. Therefore, these data were removed from the dataset used in this document, what led to some modifications on the rejection rates previously presented.

- Recalculation of the effect of hypothetical MLs for maize grain, destined for further processing, after the exclusion of samples from 2011, 2012 and 2013 and after the exclusion of outliers

  Considering that there is no guidance from CCCF on the treatment of food contaminant data and the fact that aflatoxin contamination does not follow a normal distribution, it was decided not to remove these data from the data sets considered in this document.

- Introduction of a note accompanying the proposed ML for maize grain, destined for further processing

  Considering that the MLs are proposed to food intended for human consumption, it was included a footnote explaining that the ML does not apply to maize for animal feed. Regarding the inclusion of a comment that the ML does not apply for maize for wet milling, it would be necessary clarification for better understanding of the request.

- The approach used for food for infants regarding the exclusion of data analyzed with analytical methods with LOQ > 8 µg/kg

  Considering the data set available, none of the samples analyzed with methods with LOQs higher than 8 µg/kg were positive for aflatoxins. Therefore, the approach was maintained in the present document since there was no impact on the number of samples removed considering the hypothetical limits tested.

- Following agreement on the MLs, JECFA to evaluate the exposure and risk reduction for the proposed MLs, including to determine if similar health impacts could be achieved at lower sample rejection rates

  Considering that the JECFA has a list of priorities and has already signalized that rice, wheat and sorghum needed to be addressed in future risk management activities for aflatoxins, CCCF should discuss whether the request will be forwarded to the JECFA.

- Availability of collaboratively validated aflatoxin methods that are suitable for analysis for the proposed MLs

  Considering that some countries reported that lower MLs are in force, it is possible that the results of collaborative assays for the methods used are available. Thus, member countries are encouraged to share this information with the Committee or to indicate where the data was published.

Comments provided by an individual observer organization

- The proposed MLs will constrain the capacity of humanitarian agencies of purchasing and delivering foods all over the word

  The organization establishes its own aflatoxins requirements and submits the food purchased to the analysis by accredited laboratories. Considering the report, CCCF should discuss if the MLs presented may bring difficulties to actions taken to ensure food security worldwide.

CONCLUSION KEY POINTS RAISED IN RESPONSE TO CL 2020/23/OCS-CF

10. Based on summary of the key points raised in response to CL 2020/23/OCS-CF, the MLs remained unchanged although the sample rejection rates have changed for certain MLs as highlighted in Appendix I. A number of questions have been identified in order to continue progressing work in the EWG on which further guidance from CCCF14 would be required following the advice provided by Codex members and observers in reply to CL 2021/15/OCS-CF.

RECOMMENDATIONS

11. CCCF is invited to consider:

11.1 The following questions to enable consideration of the proposed MLs for the various food categories under consideration taking into account the information provided in paragraph 9 and comments submitted by Codex members and observers.

a. Should the rejection rates adopted be the same for grains and for processed products? (Grains may have another destination, such as animal feed). What is the more appropriate rejection rate, considering the different types of products and contaminants?

b. How the outliers should be treated, since there is no harmonized procedure available in the Committee?

c. How should the maize data be evaluated, since the available data are related to the marketing of the products and there is no guarantee that they are intended exclusively for human consumption and not for animal feed?

d. Are there any methods available that have already been validated in collaborative assays that meet the limits proposed in this document?

e. Should CCCF request JECFA to carry out a dietary exposure assessment considering the MLs proposed in this document?

f. What limits does CCCF consider that can move forward in this meeting?

11.2 The proposed MLs for the various food categories as shown in Appendix I, based on the replies provided on the questions put forward in paragraph 11.1, the background information providing the rationale for the proposed MLs as contained in Appendix II and comments submitted by Codex members and observers.

11.3 The re-establishment of the EWG to continue working on proposals for MLs for total aflatoxins in certain cereals and cereal-based products, including food for infants and young children, taking into account the discussion held in plenary and the advice provided by the Committee on the points raised in paragraphs 11.1 and 11.2.

APPENDIX I

MAXMUM LEVELS FOR TOTAL AFLATOXINS IN CERTAIN CEREALS AND CEREAL-BASED PRODUCTS INCLUDING FOODS FOR INFANTS AND YOUNG CHILDREN

(For comments at Step 3
based on the replies provided to the questions
put forward in the Recommendations[7])

Food category	**Proposal 1**		**Proposal 2**	
	ML	**Sample rejection (%)**	**ML**	**Sample rejection (%)**
Maize grain, destined for further processing[ab]	20 µg/kg	4.5	15 µg/kg	5.4
Flour, meal, semolina and flakes derived from maize	15 µg/kg	1.1	10 µg/kg	1.5
Husked rice	20 µg/kg	2.1	15 µg/kg	2.7
Polished rice	8 µg/kg	0.4	4 µg/kg	1.2
Sorghum grain, destined for further processing[a]	10 µg/kg	2.0	8 µg/kg	2.7
Cereal-based Food for infants and young children[c]	2 µg/kg	0.2	1 µg/kg	7.9

[a]Destined for further processing" means intended to undergo an additional processing/treatment that has proven to reduce level of AFs before being used as an ingredient in foodstuffs, otherwise processed or offered for human consumption; [b]Does not apply to maize destined for animal feed; [c]All cereal-based foods intended for infants (up to 12 months) and young children (12 to 36 months).

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[7] CX/CF 21/14/10-Part I, paragraph 11

APPENDIX II

(For information)

INTRODUCTION

1. Aflatoxins (AFs) are considered the most important naturally occurring group of mycotoxins in the world's food supply. AFs (B_1, B_2, G_1 and G_2) were classified as human liver carcinogens by an evaluation conducted by the JECFA, with AFB1 being considered the most potent one (FAO/WHO, 1998; FAO/WHO, 2017). No tolerable daily intake was proposed since they are genotoxic carcinogens. JECFA noted, at its last toxicological evaluation on aflatoxins (FAO/WHO, 2017), that rice, wheat and sorghum needed to be addressed in future risk management activities for aflatoxins, considering their contribution to aflatoxin exposure in some parts of the world where these cereals are consumed as staple foods in the diet.

2. Since the complete elimination of aflatoxins from the food supply is not feasible, measures should be taken to control and manage worldwide contamination. At CCCF13 (2019), it was noted that the Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CXC 55 -2004) was adopted in 2003 and revised in 2017 and the logical next step for CCCF was to establish MLs for aflatoxins in some cereal and cereal-based products. Maximum Levels (MLs) for total aflatoxins have been established by the Codex Alimentarius Commission for almonds, Brazil nuts, hazelnuts, peanuts intended for further processing, pistachios and dried figs (CXS 193-1995). The focus of this document is to review occurrence data submitted to the GEMS/Food database and to propose additional MLs for total aflatoxins in cereals and cereal-based products, including food for infants and young children.

DATA ANALYSIS

3. Data on aflatoxins levels in maize grain for further processing, flour, meal, semolina and flakes derived from maize, husked and polished rice, sorghum grain and cereal-based food for infants and small children were obtained from the GEMS/Food database. Data for samples analyzed between 2007 and 2019 were extracted from the database for analysis. Worldwide occurrence of aflatoxins in cereals and products thereof was evaluated using data extracted from the GEMS/Food database as of November 2019.

4. First, data were individually analyzed and grouped into categories according to their listed "food name, food code and local food name". Final food categories were created considering the data available in the GEMS/Food database and CCCF grouping recommendations. The following data were removed from the dataset:

   a. Data that did not meet the basic criteria - For example, samples classified as maize grain but described in the local food name as canned maize (i.e., sweet corn consumed as a vegetable rather than as a cereal grain);

   b. Aggregated samples (i.e., samples reported as summary statistics rather than individually);

   c. Samples that were cooked before analysis - since Codex MLs are proposed for raw foods, the form in which they are internationally traded;

   d. Samples that did not report LOQ or LOD values and that did not have quantifiable results;

   e. Samples that did not report the exactly quantifiable result when the value was higher than the LOQ – For example, samples that reported results as less than a numerical value, but the value was higher than the LOQ reported (Results ≤ 20 µg/kg; LOQ=5);

   f. Samples that were analyzed using methods that had higher LOQs than the highest hypothetical ML considered for each food category in this document;

   g. Outliers were not removed since aflatoxins are not homogeneously distributed and therefore it is possible that samples with high AFs concentration could be found in the market. Besides that, the few high values maintained in the dataset did not impact the proposal of MLs since they had no effect on the 95 percentiles. The treatment of outliers in the data for mycotoxins should be further discussed taking into account mycotoxins' heterogeneous distribution in food samples.

5. For aflatoxins, some samples included information on individual aflatoxin (AFB_1, AFB_2, AFG_1, AFG_2), the sum of AFB_1 plus AFB_2 and total aflatoxins, which generated up to 6 entries per sample. In such cases, data were gathered according to the "serial number" provided. Samples that reported results only for AFB_2, AFG_1 or AFG_2 were excluded when it was not possible to sum individual concentrations to yield a total aflatoxin concentration using the "serial number". Considering this information, it was not possible to keep a record of the samples excluded from the dataset, since just one sample could lead to the insertion of up to six lines in the dataset.

6. Only samples intended for human consumption were maintained in the dataset, i.e. animal feed samples were not included in the analysis. Lower bound AFs concentrations were estimated considering samples below the reported LOQ as zero, since the positive detection rate for almost all food categories were less than 20%.

MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN CERTAIN CEREALS AND CEREAL-BASED PRODUCTS, INCLUDING FOOD FOR INFANTS AND YOUNG CHILDREN

7. In order to propose ML for total aflatoxins, data for each food category were organized in three different tables, containing information on the worldwide AFs occurrence, the seasonality during the period analyzed and the effects of the implementation of different hypothetical MLs on AFs intake and sample rejection. Different MLs were proposed according to the contaminant distribution profile of each food group.

8. Since the risk assessment for AFs was conducted by JECFA in 2017 (JECFA49), dietary exposure to aflatoxins was estimated in this document only to support the risk management decisions. Dietary exposure to aflatoxins through the consumption of maize grain for further processing, flour, meal, semolina and flakes derived from maize, husked and polished rice, and sorghum grain for further processing was estimated using the GEMS/Food occurrence data and mean consumption data obtained from the 17 GEMS/Food Cluster Diets. Consumption data were chosen in order to best represent the food categories evaluated. Annex I of Appendix I shows countries that belong to each GEMS/Food Cluster and consumption data for each cluster diets can be found in Annex II. Dietary exposure to AFs through the consumption of food for infants and young children was not evaluated since there were no consumption data available for the GEMS/Food Cluster Diets for such foods.

9. Tables 1, 2 and 3 show data on the occurrence and concentration of AFs in maize grain destined for further processing. A total of 1,189,321 samples were analyzed and 10% were positive for one or more AFs. The mean of positive samples was 60.7 µg/kg, mean and the 95th percentile (P95) of the lower bound were, respectively, 6.1 µg/kg and 18 µg/kg. Most samples analyzed came from the United States of America (USA) (99.6%). The highest lower-bound mean concentrations were found in samples submitted by the USA (6.1 µg/kg), Philippines (3.8 µg/kg) and Indonesia (3.3 µg/kg). 2007, 2012, 2009,, 2013 and 2011 showed the highest incidence levels of AFs, with respectively, 70%, 27.5%, 16.4%, 14.6% and 13.4% of samples containing detectable concentrations of one or more AFs. Table 3 shows that mean of the lower bound ranged from 1.0 µg/kg in samples submitted by Asian countries to 6.1 µg/kg on samples from American countries.

Table 1. GEMS/Food data on the occurrence and concentrations of AFs in maize grain destined for further processing.

Country	Number and proportion of positive samples[a] (%)	Mean of positive samples (range) - µg/kg	Lower bound[b] (µg/kg)	
			Mean	P95[c]
Brazil	0/36 (0)	<LOQ	<LOQ	-
Canada	29/64 (45.3)	6.4 (0.1-90)	2.9	7.9
European Union	1,070/4,045 (26.5)	7.5 (0.02-226)	2.0	6.7
Indonesia	14/20 (70.0)	4.7 (0.3-16.2)	3.3	16.2
Philippines	3/7 (42.9)	8.8 (2.0-14.8)	3.8	-
Saudi Arabia	4/37 (10.8)	3.8 (0.1-9.9)	0.4	-
Singapore	0/27 (0)	<LOQ	<LOQ	-
Thailand	0/20 (0)	<LOQ	<LOQ	-
USA	118,161/1,185,065 (10.0)	61.2 (0.02-9,928)	6.1	18.0
Total	**119,281/1,189,321 (10.0)**	**60.7 (0.02-9,928)**	**6.1**	**18.0**

[a]Samples analyzed with methods with LOQ higher than 20 µg/kg were removed; [b]LB: mean of all samples (samples below LOQ were considered as zero); [c]P95 was only estimated when the number of positive samples were ≥10.

Table 2. GEMS/Food data on the occurrence and concentrations of AFs in maize grain destined for further processing organized by year of sampling.

Year	Number and proportion of positive samples[a] (%)	Mean of positive samples (range) - µg/kg	Lower bound[b] (µg/kg)	
			Mean	P95[c]
2007	14/20 (70.0)	3.3 (0.07-16.2)	3.3	16.2
2008	0/4 (0)	<LOQ	<LOQ	-
2009	9/55 (16.4)	12.8 (0.8-56.2)	2.1	9.2
2010	2,542/37,619 (6.8)	61.4 (2.0-2,700)	4.1	7.0
2011	21,463/160,671 (13.4)	78.2 (0.2-3,200)	10.4	62.0
2012	44,444/161, 504 (27.5)	83.5 (0.1-6,117)	23	96.0
2013	22,112/151,207 (14.6)	38.1 (0.1-9,928)	5.6	20.0
2014	5,642/102,865 (5.5)	16.1 (0.1-2,400)	0.9	5.3
2015	3,929/102,824 (3.8)	47 (0.2-5,341)	1.8	0.0
2016	4,690/120,291 (3.9)	37.8 (0.02-1,000)	1.5	0.0
2017	5,408/121,017 (4.5)	43.3 (0.1-8447)	1.9	0.0
2018	5,943/144,886 (4.1)	18.6 (0.02-919)	0.8	0.0
2019	3,085/86,319 (3.6)	17.8 (0.2-997)	0.6	0.0
NS	0/39 (0)	<LOQ	<LOQ	-
Total	**119,281/1,189,321 (10.0)**	**60.7 (0.02-9,928)**	**6.1**	**18.0**

NS: year of sampling was not specified; [a]Samples analyzed with methods with LOQ higher than 20 µg/kg were removed; [b]LB: mean of all samples (samples below LOQ were considered as zero); [c]P95 was only estimated when the number of positive samples were ≥10.

Table 3. GEMS/Food data on the occurrence and concentrations of AFs in maize grain destined for further processing organized by continent.

Continent	Number and proportion of positive samples[a] (%)	Mean of positive samples (range) - µg/kg	Lower bound[b] (µg/kg)	
			Mean	P95[c]
America	118,190/1,185,165 (10.0)	61.2 (0.02-9928)	6.1	18
Asia	21/111 (18.9)	5.1 (0.05-16.2)	1.0	5.4
Europe	1,070/4,045 (26.5)	7.5 (0.02-226)	2.0	6.7
Total	**119,281/1,189,321 (10.0)**	**60.7 (0.02-9928)**	**6.1**	**18.0**

[a]Samples analyzed with methods with LOQ higher than 20 µg/kg were removed; [b]LB: mean of all samples (samples below LOQ were considered as zero); [c]P95 was only estimated when the number of positive samples were ≥10.

10. Table 4 shows the impact of the implementation of MLs on exposure and on rejection rates for AFs in maize grain destined for further processing. The intake reduction was estimated for the Cluster Diet with the highest consumption of the food category being examined (worst case scenario -G06) and the sample rejection rate was calculated using all samples in the data set. Four different hypothetical MLs were considered, based on the AFs contamination profile of maize grain data submitted to the GEMS/Food database. Among the four values considered, the establishment of an ML of 20 µg/kg seems to be the most adequate value, both for intake reduction (90.2%; G06) as well as the sample rejection rate (4.5%).

Table 4. Effect of hypothetical MLs on aflatoxins intake through the consumption of maize grain for Cluster G06 (highest consumption pattern).

ML (µg/kg)	Mean AF (µg/kg)	Intake (ng/kg bw per day)[a]	Intake reduction (%)	Sample rejection (%)[b]
No limits	6.1	1.25	-	-
20	0.5	0.12	90.2	4.5
15	0.4	0.08	93.4	5.4
10	0.4	0.08	93.4	5.4
8	0.2	0.04	97.0	7.4

[a]Consumption data used: maize, raw; G06=12.33 g/person (mean consumption). [b]Percentage of samples above proposed MLs for AFs considering samples from all Clusters Diets for this food category.

11. Considering the adoption of a ML of 20 µg/kg for maize grain, the rejection rate would not exceed 5% for any of the countries that submitted samples to the GEMS/Food at this time and would be the following for all samples collected in these years: 2011 (8.2%) and 2012 (17.4%).

12. Tables 5, 6 and 7 show data on the occurrence and concentration of AFs in flour, meal, semolina and flakes derived from maize. A total of 3,265 samples were submitted to the GEMS/Food database and 13% were positive for one or more AFs. Mean of positive samples was 13.6 µg/kg, mean and the P95 of the lower bound were respectively 1.8 µg/kg and 1.7 µg/kg. Most samples analyzed came from the EU (55%) and the USA (30%). The highest mean level of the lower bound was found in samples submitted by Singapore (13.9 µg/kg) and Philippines (4.9 µg/kg). The years of 2008 and 2013 showed the highest incidence levels of AFs, with, respectively, 100% (2 of 2 samples) and 28.3%, of samples being positive.

Table 5. GEMS/Food data on the occurrence and concentrations of AFs in flour, meal, semolina and flakes derived from maize.

Country	Number and proportion of positive samples[a] (%)	Mean of positive samples (range) - µg/kg	Lower bound[b] (µg/kg)	
			Mean	P95[c]
Argentina	1/81 (1.2)	0.1 (0.1)	0.002	-
Brazil	0/30 (0)	<LOQ	<LOQ	-
Canada	32/209 (15.3)	6.1 (0.3-18.7)	0.9	8.8
European Union	175/1,799 (9.7)	5.8 (0.01-790)	0.6	0.6
Philippines	1/1 (100)	4.9 (4.9)	4.9	-
Singapore	86/165 (52.1)	26.7 (0.05-476)	13.9	25.7
USA	131/980 (13.4)	17.4 (0.4-277.9)	2.3	5.6
Total	**426/3,265 (13.0)**	**13.6 (0.01-790)**	**1.8**	**1.7**

[a]Samples analyzed with methods with LOQ higher than 15 µg/kg were removed; [b]LB: mean of all samples (samples below LOQ were considered as zero); [c]P95 was only estimated when the number of positive samples were ≥10.

Table 6. GEMS/Food data on the occurrence and concentrations of AFs in flour, meal, semolina and flakes derived from maize, organized by year of sampling.

Year	Number and proportion of positive samples[a] (%)	Mean of positive samples (range) - µg/kg	Lower bound[b] (µg/kg) Mean	Lower bound[b] (µg/kg) P95[c]
2008	2/2 (100)	0.4 (0.4)	0.4	-
2009	20/136 (14.7)	4.7 (0.2-19.8)	0.7	5.2
2010	8/120 (6.7)	1.2 (0.2-4.4)	0.1	-
2011	20/141 (14.2)	2.1 (0.2-5.0)	0.3	2.8
2012	56/529 (10.6)	1.5 (0.03-10.1)	0.2	0.6
2013	52/184 (28.3)	0.9 (0.1-4.9)	0.3	1.1
2014	43/248 (17.3)	26.6 (0.07-476)	4.6	1.2
2015	15/224 (6.7)	18.1 (0.02-221)	1.2	0.0
2016	96/546 (17.6)	29.9 (0.01-790)	5.3	3.1
2017	48/566 (8.5)	16.5 (0.06-394)	1.4	0.9
2018	30/254 (11.8)	7.7 (0.84-52.9)	0.9	3.0
2019	7/155 (4.5)	2.3 (0.1-6.6)	0.1	-
NS	29/160 (18.1)	6.3 (0.1-18.7)	1.1	9.7
Total	**426/3,265 (13.0)**	**13.6 (0.01-790)**	**1.8**	**1.7**

NS: year of sampling was not specified; [a]Samples analyzed with methods with LOQ higher than 15 µg/kg were removed; [b]LB: mean of all samples (samples below LOQ were considered as zero); [c]P95 was only estimated when the number of positive samples were ≥10.

Table 7. GEMS/Food data on the occurrence and concentrations of AFs in flour, meal, semolina and flakes derived from maize, organized by continent.

Continent	Number and proportion of positive samples[a] (%)	Mean of positive samples (range) - µg/kg	Lower bound[b] (µg/kg) Mean	Lower bound[b] (µg/kg) P95[c]
America	164/1,300 (12.6)	15.1 (0.1-277.9)	1.9	4.5
Asia	87/166 (52.4)	26.4 (0.1-476)	13.8	24.9
Europe	175/1,799 (9.7)	5.8 (0.01-790)	0.6	0.6
Total	**426/3,265 (13.0)**	**13.6 (0.01-790)**	**1.8**	**1.7**

[a]Samples analyzed with methods with LOQ higher than 15 µg/kg were removed; [b]LB: mean of all samples (samples below LOQ were considered as zero); [c]P95 was only estimated when the number of positive samples were ≥10.

13. Table 8 shows the impact of hypothetical MLs for AFs in flour, meal, semolina and flakes derived from maize. Among the five values tested, the data available suggest the establishment of a ML of 10 µg/kg, considering both the intake reduction (90%; G13) as well as the sample rejection rate (1.5%). Considering the adoption of a ML of 10 µg/kg flour, meal, semolina and flakes derived from maize, the rejection rate would exceed 5% only for samples submitted by Singapore (6.1%). The ML of 20 µg/kg was not considered viable since previous discussion papers on aflatoxins in cereals have already showed the effects of processing on the reduction of total AFs content.

Table 8. Effect of hypothetical MLs on aflatoxins intake through the consumption of flour, meal, semolina and flakes derived from maize for cluster G13 (highest consumption pattern).

ML (µg/kg)	Mean AF (µg/kg)	Intake (ng/kg bw per day)[a]	Intake reduction (%)	Sample rejection (%)[b]
No limits	1.8	2.8	-	-
20	0.3	0.4	84.4	1.0
15	0.25	0.4	85.9	1.1
10	0.2	0.3	88.5	1.5
8	0.18	0.3	89.6	1.7
4	0.09	0.1	94.8	3.3

[a]Consumption data used: maize, flour (white flour and wholemeal); G13= 94.34 g/person (mean consumption). [b]Percentage of samples above proposed MLs for AFs considering samples from all Clusters Diets for this food category.

14. Tables 9, 10 and 11 show data on the occurrence and concentration of AFs in husked rice. 22.3% of the 672 samples submitted to the GEMS/Food database were positive for at least one aflatoxin. Mean of positive samples was 8.5 µg/kg, mean and the P95 of the lower bound were 1.9 µg/kg and 8.0 µg/kg. USA, EU and Thailand contributed with the largest dataset of husked rice, representing 43%, 29% and 13% of the samples, respectively. The highest mean level of the lower bound was found in samples submitted by Thailand (3.4 µg/kg) and USA (2.9 µg/kg).The highest incidence levels of AFs were found in the years of 2008 (48%), 2017 (43%), 2009 (33%) and 2010 (30%).

Table 9. GEMS/Food data on the occurrence and concentrations of AFs in husked rice.

Country	Number and proportion of positive samples[a] (%)	Mean of positive samples (range) - µg/kg	Lower bound[b] (µg/kg)	
			Mean	P95[c]
Brazil	2/19 (10.5)	0.3 (0.3)	0.03	-
Canada	16/43 (37.2)	0.8 (0.01-7.1)	0.3	1.4
European Union	63/195 (32.3)	1.8 (0.1-10.3)	0.6	4.2
Singapore	2/35 (5.7)	0.1 (0.1-0.18)	0.01	-
Thailand	20/90 (22.2)	15.5 (0.3-104)	3.4	13.6
USA	47/290 (16.2)	17.8 (0.6-132)	2.9	11.1
Total	**150/672 (22.3)**	**8.5 (0.01-132)**	**1.9**	**8.0**

[a]Samples analyzed with methods with LOQ higher than 15 µg/kg were removed; [b]LB: mean of all samples (samples below LOQ were considered as zero); [c]P95 was only estimated when the number of positive samples were ≥10.

Table 10. GEMS/Food data on the occurrence and concentrations of AFs in husked rice organized by year of sampling.

Year	Number and proportion of positive samples[a] (%)	Mean of positive samples (range) - µg/kg	Lower bound[b] (µg/kg)	
			Mean	P95[c]
2008	10/21 (47.6)	1.1 (0.01-7.1)	0.5	1.9
2009	12/36 (33.3)	0.3 (0.01-1.4)	0.09	0.3
2010	12/41 (29.3)	0.3 (0.2-0.4)	0.07	0.3
2011	0/2 (0)	<LOQ	<LOQ	-
2012	4/22 (18.2)	3.9 (3.6-4.2)	0.7	-
2013	16/59 (26.7)	4.9 (0.7-10.3)	1.3	9.5
2014	0/37 (0)	<LOQ	<LOQ	-
2015	4/44 (9.1)	22.3 (1.3-82.1)	2.0	-
2016	5/62 (8.1)	3.4 (0.2-6.8)	0.3	-
2017	26/61 (42.6)	0.7 (0.1-4.9)	0.3	0.5
2018	17/64 (26.6)	16.2 (0.3-104)	4.3	26.0
2019	7/75 (9.3)	7.1 (0.3-34.5)	0.7	-
NS	37/148 (25)	19.4 (2.0-132)	4.8	17.0
Total	**159/672 (22.3)**	**8.5 (0.01-132)**	**1.9**	**8.0**

NS: year of sampling was not specified; [a]Samples analyzed with methods with LOQ higher than 15 µg/kg were removed; [b]LB: mean of all samples (samples below LOQ were considered as zero); [c]P95 was only estimated when the number of positive samples were ≥10.

Table 11. GEMS/Food data on the occurrence and concentrations of AFs in husked rice, organized by continent.

Continent	Number and proportion of positive samples[a] (%)	Mean of positive samples (range) - µg/kg	Lower bound[b] (µg/kg)	
			Mean	P95[c]
America	65/352 (18.5)	13.1 (0.01-132)	2.4	9.0
Asia	22/125 (17.6)	14.1 (0.1-104)	2.5	3.1
Europe	63/195 (32.3)	1.8 (0.1-10.3)	0.6	4.2
Total	**150/672 (22.3)**	**8.5 (0.01-132)**	**1.9**	**8.0**

[a]Samples analyzed with methods with LOQ higher than 15 µg/kg were removed; [b]LB: mean of all samples (samples below LOQ were considered as zero); [c]P95 was only estimated when the number of positive samples were ≥10.

15. Table 12 shows the impact of hypothetical MLs for husked rice. The establishment of a ML of 15 µg/kg seems the most adequate value, considering a reduction of 70% in AFs intake for cluster G03, the cluster with the highest reported consumption of rice, and a sample rejection rate of 2.7%.

Table 12. Effect of hypothetical MLs on aflatoxins intake through the consumption of husked rice for cluster G03 (highest consumption pattern).

ML (µg/kg)	Mean AF (µg/kg)	Intake (ng/kg bw per day)[a]	Intake reduction (%)	Sample rejection (%)[b]
No limits	1.9	0.98	-	-
20	0.7	0.34	65.2	2.1
15	0.66	0.29	70.5	2.7
12	0.54	0.28	71.6	2.8
10	0.47	0.25	75	3.4
8	0.34	0.18	82.1	4.9

[a]Consumption data used: rice, husked, dry (incl. paddy rice); G03=31.05 g/person (mean consumption). [b]Percentage of samples above proposed MLs for AFs considering samples from all Clusters Diets for this food category.

16. If CCCF agrees on the adoption of a ML of 15 µg/kg for husked rice, samples collected in 2018 and with no information on sampling date would exceed 5% of the rejection rate, representing, respectively, 11% and 6.1% of the samples available on the dataset.

17. Data on the occurrence and concentration of AFs in polished rice are shown in Tables 13, 14 and 15. A total of 7123 samples were submitted to the GEMS/Food database, being 20% positive for one or more AFs. Mean of positive samples was 1.4 µg/kg, mean and the P95 of the lower bound were, respectively, 0.3 µg/kg and 1.1 µg/kg. Most samples analyzed came from the EU (74%), USA (9.1%) and Thailand (8.5%). The highest mean level of the lower bound was found is samples submitted by USA (0.4 µg/kg), followed by the EU and Saudi Arabia(0.3 µg/kg). The highest incidence of AFs was found in 2008 (56%) and 2009 (56%), followed by the years of 2013 (33%), 2010 (30%) and 2011 (28%).

Table 13. GEMS/Food data on the occurrence and concentrations of AFs in polished rice.

Country	Number and proportion of positive samples[a] (%)	Mean of positive samples (range) - µg/kg	Lower bound[b] (µg/kg)	
			Mean	P95[c]
Brazil	1/71 (1.4)	4.9 (4.9)	0.07	-
Canada	46/80 (57.5)	0.4 (0.002-2.9)	0.2	1.6
European Union	1,249/5,271 (23.7)	1.2 (0.01-251)	0.3	1.2
Saudi Arabia	39/401 (9.7)	2.9 (0.01-27.1)	0.3	0.7
Singapore	3/53 (5.7)	0.1 (0.06-0.16)	0.01	-
Thailand	82/602 (13.6)	1.5 (0.3-28.9)	0.2	0.6
USA	28/645 (4.3)	8.7 (0.6-88)	0.4	0.0
Total	**1,448/7,123 (20.3)**	**1.4 (0.002-251)**	**0.3**	**1.1**

[a]Samples analyzed with methods with LOQ higher than 12 µg/kg were removed; [b]LB: mean of all samples (samples below LOQ were considered as zero); [c]P95 was only estimated when the number of positive samples were ≥10.

Table 14. GEMS/Food data on the occurrence and concentrations of AFs in polished rice organized by year of sampling.

Year	Number and proportion of positive samples[a] (%)	Mean of positive samples (range) - µg/kg	Lower bound[b] (µg/kg)	
			Mean	P95[c]
2008	24/43 (55.8)	0.4 (0.01-2.9)	0.2	1.5
2009	209/374 (55.9)	0.9 (0.002-13.0)	0.5	2.7
2010	162/533 (30.4)	1.1 (0.02-13.6)	0.3	1.6
2011	164/575 (28.5)	1.4 (0.01-17.0)	0.4	1.6
2012	80/661 (12.1)	1.1 (0.03-8.7)	0.1	0.8
2013	211/640 (33)	0.7 (0.01-7.0)	0.2	0.8
2014	178/991 (18.0)	0.9 (0.01-9.0)	0.2	0.8
2015	100/616 (16.2)	3.8 (0.01-251)	0.6	0.9
2016	125/857 (14.6)	1.4 (0.01-27.1)	0.2	0.9
2017	105/624 (16.8)	1.0 (0.01-6.2)	0.2	1.1
2018	64/463 (13.8)	1.9 (0.3-28.9)	0.3	0.9
2019	1/46 (2.2)	0.50 (0.5)	0.01	0.0
NS	25/700 (3.6)	9.25 (0.06-88.0)	0.3	0.0
Total	**1,448/7,123 (20.3)**	**1.4 (0.002-251)**	**0.3**	**1.1**

NS: year of sampling was not specified; [a]Samples analyzed with methods with LOQ higher than 12 µg/kg were removed; [b]LB: mean of all samples (samples below LOQ were considered as zero); [c]P95 was only estimated when the number of positive samples were ≥10.

Table 15. GEMS/Food data on the occurrence and concentrations of AFs in polished rice, organized by continent.

Continent	Number and proportion of positive samples[a] (%)	Mean of positive samples (range) - µg/kg	Lower bound[b] (µg/kg)	
			Mean	P95[c]
America	75/796 (9.4)	3.52 (0.002-88)	0.33	0.2
Asia	124/1,056 (11.7)	1.93 (0.01-29)	0.23	0.6
Europe	1,249/5,271 (23.7)	1.2 (0.01-251)	0.3	1.2
Total	**1,448/7,123 (20.3)**	**1.4 (0.002-251)**	**0.3**	**1.1**

[a]Samples analyzed with methods with LOQ higher than 12 µg/kg were removed; [b]LB: mean of all samples (samples below LOQ were considered as zero); [c]P95 was only estimated when the number of positive samples were ≥10.

18. The impact of hypothetical MLs for AFs in polished rice is shown in Table 16. Considering the data available, the implementation of a ML of 8 µg/kg seems suitable since it will reduce AFs intake in 70% (G09) and would generate a rejection rate of only 0.4%. If CCCF agrees with the ML suggested (8 µg/kg), the rejection rate would not exceed 5% for any set of samples submitted to the GEMS/Food database.

Table 16. Effect of hypothetical MLs on aflatoxins intake through the consumption of polished rice for cluster G09 (highest consumption pattern).

ML (µg/kg)	Mean AF (µg/kg)	Intake (ng/kg bw per day)[a]	Intake reduction (%)	Sample rejection (%)[b]
No limits	0.28	1.34	-	-
12	0.20	0.94	30	0.22
10	0.19	0.92	31.6	0.27
8	0.18	0.87	35	0.4
4	0.14	0.66	51	1.2

[a]Consumption data used: rice. polished. dry; G09= 262.1 g/person (mean consumption). [b]Percentage of samples above proposed MLs for AFs considering samples from all Clusters Diets for this food category.

19. Tables 17, 18 and 19 show data on the occurrence and concentration of AFs in sorghum grain destined for further processing. 6% of the 13,168 samples submitted to the GEMS/Food database were positive for at least one aflatoxin. Mean of positive samples was 12.6 µg/kg, and the P95 of the lower bound were 0.7 µg/kg and 6.0 µg/kg. Almost all data of sorghum grain were submitted by the USA (99% of the samples). The highest mean level of the lower bound was found is samples submitted by Indonesia (9.9 µg/kg). The highest incidence levels of AFs were found in the years of 2010 (90%) and 2009 (33%).

Table 17. GEMS/Food data on the occurrence and concentrations of AFs in sorghum grain destined for further processing.

Country	Number and proportion of positive samples[a] (%)	Mean of positive samples (range) - µg/kg	Lower bound[b] (µg/kg)	
			Mean	P95[c]
Indonesia	17/17 (100)	9.9 (2.3-13.9)	9.9	13.8
Japan	1/9 (11.1)	0.4 (0.4)	0.04	-
Republic of Korea	5/93 (5.4)	4.4(0.3-10.8)	0.2	-
USA	749/13,049 (5.7)	12.7 (5.0-204)	0.7	5.0
Total	**772/13,168 (5.9)**	**12.6 (0.3-204)**	**0.7**	**6.0**

[a]Samples analyzed with methods with LOQ higher than 20 µg/kg were removed; [b]LB: mean of all samples (samples below LOQ were considered as zero); [c]P95 was only estimated when the number of positive samples were ≥10.

Table 18. GEMS/Food data on the occurrence and concentrations of AFs in sorghum grain destined for further processing organized by year of sampling.

Year	Number and proportion of positive samples[a] (%)	Mean of positive samples (range) - µg/kg	Lower bound[b] (µg/kg)	
			Mean	P95[c]
2008	0/1 (0)	<LOQ	<LOQ	-
2009	1/3 (33.3)	0.4 (0.4)	0.1	-
2010	18/20 (90.0)	9.4 (0.3-13.9)	8.5	13.8
2011	0/12 (0)	<LOQ	<LOQ	-
2012	4/84 (4.8)	5.5 (0.6-10.8)	0.3	-
NS	749/13,048 (5.7)	12.7 (5.0-204)	0.7	5.0
Total	**772/13,168 (5.9)**	**12.6 (0.3-204)**	**0.7**	**6.0**

NS: year of sampling was not specified; [a]Samples analyzed with methods with LOQ higher than 20 µg/kg were removed; [b]LB: mean of all samples (samples below LOQ were considered as zero); [c]P95 was only estimated when the number of positive samples were ≥10.

Table 19. GEMS/Food data on the occurrence and concentrations of AFs in sorghum grain destined for further processing, organized by continent.

Continent	Number and proportion of positive samples[a] (%)	Mean of positive samples (range) - µg/kg	Lower bound[b] (µg/kg)	
			Mean	P95[c]
America	749/13,049 (5.7)	12.7 (5.0-204)	0.7	5.0
Asia	23/119 (19.3)	8.3 (0.3-13.9)	1.6	13.6
Total	**772/13,168 (5.9)**	**12.6 (0.3-204)**	**0.7**	**6.0**

[a]Samples analyzed with methods with LOQ higher than 20 µg/kg were removed; [b]LB: mean of all samples (samples below LOQ were considered as zero); [c]P95 was only estimated when the number of positive samples were ≥10.

20. Table 20 shows the impact of hypothetical MLs for sorghum grain destined for further processing. The establishment of a ML of 8 µg/kg seems to be reasonable, considering a reduction of 73% in AFs intake for cluster G12 and a sample rejection rate of 2.7%.

Table 20. Effect of hypothetical MLs on aflatoxins intake through the consumption sorghum grain destined for further processing for cluster G12 (highest consumption pattern).

ML (µg/kg)	Mean AF (µg/kg)	Intake (ng/kg bw per day)[a]	Intake reduction (%)	Sample rejection (%)[b]
No limits	0.7	0.09	-	-
20	0.5	0.06	32.9	0.4
15	0.4	0.05	45.6	1.0
10	0.3	0.03	63.7	2.0
8	0.2	0.02	72.6	2.7

[a]Consumption data used: sorghum, raw (incl flour. incl beer); G12= 7.12 g/person (mean consumption). [b]Percentage of samples above proposed MLs for AFs considering samples from all Clusters Diets for this food category

21. If CCCF agrees on the adoption of a ML of 8 µg/kg for sorghum grain destined for further processing, samples submitted by Indonesia and samples collected on 2010 would exceed 5% of the rejection rate, representing, respectively, 70% and 60% of the samples available on the dataset of the category analyzed.

22. Data on the occurrence and concentration of AFs in food for infants and young children are shown in Tables 21, 22 and 23. A total of 4,145 samples were submitted to the GEMS/Food database, being 5% positive for one or more AFs. Mean of positive samples was 0.5 µg/kg, mean and the P95 of the lower bound were, respectively, 0.02 µg/kg and 0.0 µg/kg. Most samples analyzed were submitted by the EU (83.5%), Singapore (7.4%) and USA (5.6%). The highest mean level of the lower bound was found is samples submitted by USA (0.2 µg/kg). The highest incidence of AFs was found in 2008 (20%), followed by the years of 2009 (14%) and 2013 (10%).

Table 21. GEMS/Food data on the occurrence and concentrations of AFs in cereal-based food for infants and young children.

Country	Number and proportion of positive samples[a] (%)	Mean of positive samples (range) - µg/kg	Lower bound[b] (µg/kg)	
			Mean	P95[c]
Argentina	0/4	<LOQ	<LOQ	-
Brazil	0/38 (0)	<LOQ	<LOQ	-
Canada	0/50 (0)	<LOQ	<LOQ	-
European Union	151/3,461 (4.4)	0.2 (0.006-2.1)	0.01	0.0
Hong Kong	6/20 (30)	0.2 (0.01-1.0)	0.05	-
Republic of Korea	0/21 (0)	<LOQ	<LOQ	-
Saudi Arabia	0/14 (0)	<LOQ	<LOQ	-
Singapore	18/306 (5.9)	0.2 (0.05-0.7)	0.01	0.1
USA	18/231 (7.8)	3.0 (1.0-7.4)	0.2	0.5
Total	**193/4,145 (4.7)**	**0.5 (0.006-7.4)**	**0.02**	**0.0**

[a]Samples analyzed with methods with LOQ higher than 8µg/kg were removed; [b]LB: mean of all samples (samples below LOQ were considered as zero); [c]P95 was only estimated when the number of positive samples were ≥10.

Table 22. GEMS/Food data on the occurrence and concentrations of AFs in cereal-based food for infants and young children organized by year of sampling.

Year	Number and proportion of positive samples[a] (%)	Mean of positive samples (range) - µg/kg	Lower bound[b] (µg/kg)	
			Mean	P95[c]
2008	1/5 (20)	2.1 (2.1)	0.4	-
2009	22/156 (14.1)	0.2 (0.05-0.3)	0.03	0.4
2010	29/470 (6.2)	0.2 (0.05-0.7)	0.01	0.05
2011	6/278 (2.2)	0.07 (0.05-0.2)	0.002	-
2012	4/568 (0.7)	33.3 (0.02-50)	0.6	-
2013	24/236 (10.2)	0.1 (0.006-0.2)	0.01	0.05
2014	49/562 (8.7)	0.2 (0.01-1.5)	0.02	0.05
2015	9/796 (1.1)	0.05 (0.01-0.1)	0.001	-
2016	28/320 (8.8)	2.2 (0.02-7.4)	0.13	0.1
2017	13/364 (3.6)	0.04 (0.01-0.1)	0.001	0.0
2018	0/27 (0)	<LOQ	<LOQ	-
2019	0/2 (0)	<LOQ	<LOQ	-
NS	8/361 (2.2)	0.2 (0.2-0.3)	0.005	-
Total	**193/4,145 (4.7)**	**0.5 (0.006-7.4)**	**0.02**	**0.0**

NS: year of sampling was not specified; [a]Samples analyzed with methods with LOQ higher than 8µg/kg were removed; [b]LB: mean of all samples (samples below LOQ were considered as zero); [c]P95 was only estimated when the number of positive samples were ≥10.

Table 23. GEMS/Food data on the occurrence and concentrations of AFs in cereal-based food for infants and young children, organized by continent.

Continent	**Number and proportion of positive samples[a] (%)**	**Mean of positive samples (range) - μg/kg**	**Lower bound[b] (μg/kg)**	
			Mean	**P95[c]**
America	18/323 (5.6)	3.0 (1.1-7.4)	0.1	0.0
Asia	24/361 (6.6)	0.2 (0.01-1.0)	0.01	0.05
Europe	151/3,461 (4.4)	3.2 (0.01-50)	0.1	0.0
Total	**193/4,145 (4.7)**	**0.5 (0.006-7.4)**	**0.02**	**0.0**

[a] Samples analyzed with methods with LOQ higher than 8 μg/kg were removed; [b] LB: mean of all samples (samples below LOQ were considered as zero); [c] P95 was only estimated when the number of positive samples were ≥10.

23. The impact of hypothetical MLs for AFs in food for infants and young children is shown in Table 24. Dietary exposure to AFs through the consumption of food for infants and young children was not estimated since this food category is intended for consumption by a specific population group and worldwide consumption data for this group is not available. However, infants and young children are of great concern regarding contaminants exposure and, therefore, the effect of establishment of a ML on sample rejection was evaluated for this food category.

24. Considering the data available and the susceptibility of infants and young children, the implementation of a ML of 2 μg/kg seems suitable since would result in a rejection rate of only 0.2% of samples available at the international trade level. If CCCF agrees with the ML suggested (2 μg/kg), the rejection rate would not exceed 5% in any of the scenarios evaluated.

Table 24. Effect of the implementation of different MLs for aflatoxins in cereal-based food for infants and young children (only cereal-foods).

ML (μg/kg)	**Mean AF (μg/kg)**	**Sample rejection (%)**
No limits	0.018	-
8	0.018	0.0
6	0.014	0.05
4	0.011	0.1
2	0.009	0.2
1	0.005	7.8

25. Considering all data available at the GEMS/Food database and the scenarios tested above, the following MLs are being suggested for total AFs. The proposed MLs for each food category were based both on the intake reduction and sample rejection (less than 5%). Those MLs are a reasonable choice for the food categories selected, since they greatly contributed to AFs intake reduction and did not result in a large withdrawal of samples from international trade.

Table 25. MLs proposed for total aflatoxins in cereals and cereal-based products.

Food category	**Proposal 1**		**Proposal 2**	
	ML	**Sample rejection (%)**	**ML**	**Sample rejection (%)**
Maize grain, destined for further processing[a]	20 µg/kg	4.5	15 µg/kg	5.4
Flour, meal, semolina and flakes derived from maize	15 µg/kg	1.1	10 µg/kg	1.5
Husked rice	20 µg/kg	2.1	15 µg/kg	2.7
Polished rice	8 µg/kg	0.4	4 µg/kg	1.2
Sorghum grain, destined for further processing[a]	10 µg/kg	2.0	8 µg/kg	2.7
Cereal-based food for infants and young children[b]	2 µg/kg	0.2	1 µg/kg	7.8

[a] "Destined for further processing" means intended to undergo an additional processing/treatment that has proven to reduce level of AFs before being used as an ingredient in foodstuffs, otherwise processed or offered for human consumption; [b]All cereal foods intended for infants (up to 12 months) and young children (12 to 36 months).

26. The fact that the MLs suggested above were proposed based on data available at the GEMS/Food database, submitted mainly by the EU and USA is a drawback, since it may not be representative of AFs occurrence in cereal-based staple foods across all the GEMS/Food Cluster Diets. However, considering that calls for data on AFs in cereals and cereals-based products have been issued repeatedly since 2014, and a more representative dataset did not become available, it is reasonable that MLs for these food groups should be established based on the present dataset despite its shortcomings, considering the toxicological relevance of the implementation of these maximum levels in order to reduce AFs exposure worldwide.

27. Table 26 shows the profile of aflatoxins content in food categories evaluated in this paper. Data available showed that AFB1 is the most prevalent mycotoxin, representing up to 90% of total aflatoxins found in samples analyzed.

Table 26. Profile of aflatoxins content in food categories evaluated in this paper.

Food category	**% AFB1/AFs[a]**
Maize grain, destined for further processing[a]	95
Flour, meal, semolina and flakes derived from maize	90
Husked rice	78
Polished rice	92
Sorghum grain	95
Cereal-based Food for infants and young children[b]	92

[a] typical proportion of aflatoxin B1 (AFB1) occurrence in naturally contaminated samples according to the data submitted to the GEMS/Food database. AFs = AFB1+AFB2+AFG1+AFG2

Annex I of Appendix II: GEMS/Food 17 Cluster

Table 1. Countries included in each GEMS/Food Cluster Diets.

Cluster	Countries
G01	Afghanistan, Algeria, Azerbaijan, Iraq, Jordan, Libya, Mauritania, Mongolia, Morocco, Occupied Palestinian Territory, Pakistan, Syrian Arab Republic, Tunisia, Turkmenistan, Uzbekistan, Yemen
G02	Albania, Bosnia and Herzegovina, Georgia, Kazakhstan, Kyrgyzstan, Montenegro, Republic of Moldova, Ukraine
G03	Angola, Benin, Burundi, Cameroon, Congo, Côte d'Ivoire, Democratic Republic of the Congo, Ghana, Guinea, Liberia, Madagascar, Mozambique, Paraguay, Togo, Zambia
G04	Antigua and Barbuda, Bahamas, Barbados, Brunei Darussalam, French Polynesia, Grenada, Israel, Jamaica, Kuwait, Netherlands Antilles, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Saudi Arabia, United Arab Emirates
G05	Argentina, Bolivia, Brazil, Cape Verde, Chile, Colombia, Costa Rica, Djibouti, Dominican Republic, Ecuador, El Salvador, Guatemala, Guyana, Honduras, India, Malaysia, Maldives, Mauritius, Mexico, New Caledonia, Nicaragua, North Macedonia, Panama, Peru, Seychelles, South Africa, Suriname, Tajikistan, Trinidad and Tobago, Venezuela
G06	Armenia, Cuba, Egypt, Greece, Iran, Lebanon, Turkey
G07	Australia, Bermuda, Finland, France, Iceland, Luxembourg, Norway, Switzerland, United Kingdom, Uruguay
G08	Austria, Germany, Poland, Spain
G09	Bangladesh, Cambodia, China, Democratic People’s Republic of Korea, Guinea Bissau, Indonesia, Lao People’s Democratic Republic, Myanmar, Nepal, Philippines, Sierra Leone, Thailand, Timor Leste, Viet Nam
G10	Belarus, Bulgaria, Canada, Croatia, Cyprus, Estonia, Italy, Japan, Latvia, Malta, New Zealand, Republic of Korea, Russian Federation, United States of America
G11	Belgium, Netherlands
G12	Belize, Dominica
G13	Botswana, Burkina Faso, Central African Republic, Chad, Eswatini, Ethiopia, Gambia, Haiti, Kenya, Malawi, Mali, Namibia, Niger, Nigeria, Senegal, Somalia, Sudan, United Republic of Tanzania, Zimbabwe
G14	Comoros, Fiji Islands, Kiribati, Papua New Guinea, Solomon Islands, Sri Lanka, Vanuatu
G15	Czechia, Denmark, Hungary, Ireland, Lithuania, Portugal, Romania, Serbia, Slovakia, Slovenia, Sweden
G16	Gabon, Rwanda, Uganda
G17	Samoa, São Tome and Principe

Annex II of Appendix II: GEMS/Food Consumption Data

Table 1a. Consumption data obtained from the GEMS/Food Cluster Diets - G01 to G08 (g/person/day).

Food category	GO1	G02	G03	G04	G05	G06	G07	G08
Maize raw	0.6	NC	0.6	NC	1.2	12.3	NC	NC
Maize flour	22.7	35.6	87.3	34.9	46.7	49.1	14.3	12.9
Rice husked	1.2	1.3	31.1	4.8	0.3	2.2	2.4	1.6
Rice polished	34.2	10.4	41.7	82.4	150.2	70.5	13.4	10.8
Sorghum raw	0.0	0.01	0.0	0.01	0.0	0.0	0.0	0.0

NC= no consumption data available.

Table 1b. Consumption data obtained from the GEMS/Food Cluster Diets - G09 to G17 (g/person/day).

Food category	G09	G10	G11	G12	G13	G14	G15	G16	G17
Maize raw	1.4	NC	NC	NC	NC	0.01	0.03	NC	NC
Maize flour	19.7	12.5	4.2	52.3	94.3	8.1	28.0	56.0	28.1
Rice husked	0.4	1.1	0.0	5.0	13.5	3.5	2.0	0.01	8.8
Rice polished	266.1	57.2	12.8	62.8	30.2	218.3	12.8	15.2	51.3
Sorghum raw	0.01	1.2	0.0	7.1	0.0	0.0	0.0	0.0	0.0

NC= no consumption data available.

REFERENCES

Codex Alimentarius Commission (CAC), 1995. Codex general standard for contaminants and toxins in food and feed – Codex Standard 193-1995. Available at: http://tinyurl.com/mpkehpr.

Codex Committee on Contaminants in Foods, 2019. DISCUSSION PAPER ON THE ESTABLISHMENT OF MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN CEREALS (WHEAT, MAIZE, SORGHUM AND RICE), FLOUR AND CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN – CX/CF 19/13/15. Available at: encurtador.com.br/cnPSU

Codex Committee on Contaminants in Foods, 2019. REPORT OF THE 13rd SESSION OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS, REP19/CF. Available at: encurtador.com.br/hsTVW

Codex Alimentarius Commission, 2019. Forty-second Session, REP19/CAC. Available at: encurtador.com.br/gHTZ8

FAO/WHO, 1998. Joint FAO/WHO Expert Committee on Food Additives - Evaluation of certain food additives and contaminants: forty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives. vol. 40. WHO Food Additives Series, p. 73.

FAO/WHO, 2017. Joint FAO/WHO Expert Committee on Food Additives (JECFA) - Evaluation of certain food contaminants: eighty-third report of the Joint FAO/WHO Expert Committee on Food Additives. vol. 1002. WHO technical report series, Rome, Italy, p. 182

APPENDIX III

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